

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

CENTER FOR FOOD SAFETY, <i>et al.</i> ,)	Case No.: 3:08-cv-00484-JSW
)	
Plaintiffs,)	
)	
v.)	
)	
)	
TOM VILSACK, <i>et al.</i> ,)	
)	
Defendants,)	
)	
and)	
)	
MONSANTO COMPANY; SYNGENTA)	
SEEDS, INC.; AMERICAN SUGARBEET)	
GROWERS ASS'N, <i>et al.</i> ; BETA SEED, INC.;)	
and SESVANDERHAVE USA, INC.,)	
)	
Defendant-Intervenors.)	
_____)	

DECLARATION OF CINDY J SMITH

I, Cindy J Smith, do hereby declare as follows:

1. I make the following statements based upon my personal knowledge and experience as well as upon facts made known to me in my capacity as the Administrator of the Animal and Plant Health Inspection Service (APHIS), an Agency of the United States Department of Agriculture (USDA).

2. I have been the Administrator of APHIS since September 2007 and the Associate Administrator of APHIS since April 2007. As the Administrator of APHIS, I oversee and carry-

out APHIS' critical mission, which comprises protecting American agriculture from animal and plant pests and diseases. This protection includes regulating genetically engineered organisms that are likely to pose a plant pest risk pursuant to the Plant Protection Act (PPA), 7 U.S.C. §§ 7701 *et seq.*; protecting the health of our nation's animals, animal products and veterinary biologics by preventing, controlling and/or eliminating animal diseases and pests pursuant to the Animal Health Protection Act (AHPA), 7 U.S.C. §§ 8301 *et seq.*; promoting American agriculture and trade pursuant to the PPA and AHPA; administering the Animal Welfare Act, 7 U.S.C. §§2131 *et seq.*; and providing Federal leadership and expertise in resolving wildlife conflicts to allow people and wildlife to coexist peacefully pursuant to the Act of March 2, 1931, as amended (7 U.S.C. § 426), and the Act of December 22, 1987 (7 U.S.C. § 426c). These APHIS programs and their respective missions support the overall mission of USDA, which is to protect and promote food, agriculture, natural resources and related issues.

3. As Administrator, I have worked to ensure that APHIS' biotechnology Part 340 regulations provide safeguards to prevent any regulated genetically-engineered (GE) organisms from posing a plant pest risk. I have served as the guiding force in organizing a cooperative project with the National Association of State Departments of Agriculture, the National Plant Board, and APHIS' Plant Protection and Quarantine program to implement a State Biotechnology Inspection Pilot Project. The project included training and certifying State personnel to conduct thorough compliance inspections of low-risk field trials of GE plants under APHIS' oversight. The project has proven extremely cost-effective while delivering quality results, and it will continue in FY 2010. Also as Administrator, I led the development of the Biotechnology Quality Management System, a voluntary program to help industry and academia comply with APHIS' Part 340 requirements for conducting biotechnology field trials and moving

regulated GE organisms.

4. I began my career with APHIS in 1979. While at APHIS, I have completed a Bachelor of Science Degree in Microbiology from the University of Maryland in 1983 and a Masters Degree in Management from the University of Maryland in 2000. Throughout my career with APHIS, I have gained diverse experience by being an employee and/or manager in a number of different APHIS programs, including Plant Protection and Quarantine (PPQ), Biotechnology, Biologics and Environmental Protection (BBEP), Wildlife Services (WS), and Biotechnology Regulatory Services (BRS).

When APHIS reorganized its biotech regulatory functions in 2002 to create APHIS BRS, I became the program's first Deputy Administrator. I served as Deputy Administrator from June 2002 to April 2007. The mission of APHIS BRS is to provide plant health regulatory oversight that allows for the safe development and use of GE organisms in agriculture and the environment by ensuring that any such GE organisms are not likely to pose a plant pest risk. As the first Deputy Administrator of BRS, I was responsible for developing and conducting the full range of responsibilities associated with establishing a new BRS regulatory program. During my tenure as Deputy Administrator of BRS, I played a major role in shaping the Agency's biotechnology regulatory structure, establishing more rigorous requirements for field tests of GE crops, and initiating efforts to review and strengthen the Agency's overarching biotechnology regulations.

I also led APHIS in interagency negotiations chaired by the White House Office of Science and Technology Policy, to gain agreement on proposed biotechnology regulatory changes, and was the recipient of two USDA Honor Awards related to my leadership in biotechnology regulation.

From 2001 to 2002, I was the Associate Deputy Administrator for Wildlife Services (WS), which provides Federal leadership and expertise in resolving conflicts between humans and wildlife. While at WS, I coordinated the development of the most comprehensive organization and compilation of the program's needs and results information ever assembled in the history of the program. The information was well received by Congress, stakeholders and program managers.

APHIS' Experience in Regulating GE Plants and Crops

5. APHIS, along with the Food and Drug Administration (FDA) and Environmental Protection Agency (EPA), began regulating GE organisms in 1986, pursuant to the U.S. Government's Coordinated Framework for Biotechnology, 50 Fed. Reg. 47174 (Nov. 14, 1985). Accordingly, the Federal regulation of biotechnology is a responsibility that APHIS shares with EPA and FDA. EPA regulates pesticides, including crops with plant-incorporated protectants (pesticides intended to be produced and used in a living plant) to ensure public safety from their use, including pesticide residue on food and animal feed. FDA has primary responsibility for ensuring the safety of food and animal feed. APHIS is responsible for ensuring that any GE organisms are not likely to pose a plant pest risk. This coordinated Federal biotechnology regulatory effort is critical for reassuring consumers, industry, and other stakeholders that biotechnology-derived crops and other biotech products are rigorously regulated for safety.

6. Pursuant to its Part 340 regulations, APHIS has reviewed and issued more than 29,000 permits and notifications for field tests or movements of GE organisms subject to the Part 340 regulations. The field tests have been conducted at nearly 200,000 sites throughout the United States. Since 1992, APHIS has deregulated (granted nonregulated status to) GE plants in response to 79 petitions. These petitions include multiple GE varieties of corn, soybeans, cotton,

rapeseed, potato, tomato, squash, papaya, plum, rice, sugar beet, tobacco, alfalfa, flax, and chicory. The same GE crop varieties have also completed food safety reviews by the FDA, and, if they produce any pesticide-like substances, have also undergone further health and environmental review by the EPA. Only then can a GE crop variety be commercialized with no further Federal regulatory oversight, unless thereafter some new sound scientific evidence is found to indicate that the GE crop variety has a plant pest, food safety, or pesticide problem.

7. Many deregulated GE crops have been subsequently planted throughout the United States. These crops have been adopted broadly by both domestic and international farmers. In 2000, USDA's National Agricultural Statistics Service (NASS) began surveying farmers throughout the country to obtain statistical data on the adoption and planting of crops derived through biotechnology. In 2000, the survey estimated that 25% of corn, 61% of cotton, and 54% of soybeans planted in the United States were derived from biotechnology.

(<http://usda.mannlib.cornell.edu/usda/nass/Acre//2000s/2000/Acre-06-30-2000.pdf>).

The most recent NASS survey in 2008-2009 indicated that approximately 85% of corn, 91% of soybeans and 88% of cotton grown in the United States were derived through biotechnology (<http://usda.mannlib.cornell.edu/usda/current/Acre/Acre-06-30-2009.pdf>).

8. APHIS deregulated Round-up Ready sugar beets (RRSB) event H7-1 in March of 2005, after APHIS determined, pursuant to its Part 340 regulations, that RRSB were not likely to pose a plant pest risk and, therefore, must be granted nonregulated status. 51 Fed. Reg. 13007 (Mar. 17, 2005). The petition for RRSB deregulation was preceded by over 100 field tests of RRSB approved by BRS and based on sound scientific data and analysis BRS determined that the RRSB would not pose a plant pest risk. *Id.* Since APHIS' deregulation of RRSB, RRSB have been broadly planted by sugar beet growers throughout ten States in which sugar beets are

grown. RRSB now accounts for approximately 95% of all sugar beet root crops grown in the United States and is grown on approximately 1.4 million acres. (Colacicco Decl. at ¶ 8; Stankiewicz Gabel Decl. at ¶ 24). RRSB has completed reviews by FDA and EPA. 51 Fed. Reg. 13007 (Mar. 17, 2005). RRSB have also undergone regulatory review by other countries and are approved for production in Canada, and for use in food and feed in Australia, Canada, China, Colombia, the European Community, Japan, Mexico, New Zealand, the Philippines, Russia, Singapore and South Korea.

9. It is USDA's position that all methods of agricultural production (conventional, organic, or the use of deregulated GE varieties) can provide benefits to the environment, consumers, and the agricultural economy. Given the diversity of U.S. agriculture, the USDA Advisory Committee on Biotechnology and 21st Century Agriculture in its March 2008 consensus report agreed that fostering coexistence is an important and worthwhile goal.

(http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?contentidonly=true&contentid=AC21Reports.xml). USDA Secretary Vilsack, speaking on the topic of food security on World Food Day in October of 2009 stated, "[B]iotechnology is one strategy for more sustainable agriculture, but certainly not the only strategy. And since this is a country-led effort, we will find that there will be circumstances where biotechnology is the answer." (<http://www.america.gov/st/texttrans-english/2009/October/20091019103806eaifas0.5082056.html>). Speaking to an audience at Iowa State University in October 2009, Deputy Secretary Merrigan said, "There needs to be a strong place for organic as well as genetically engineered crops. They both have a place."

(<http://www.kglonews.com/modules.php?name=News&file=article&sid=1771>). On the same

occasion, she went on to say that the USDA Secretary talks of a “peaceful coexistence” of these types of agriculture (op. cit.)

For decades, growers have successfully cultivated crops bearing different traits, often on adjoining fields, whether such traits were introduced into the crops by conventional means or genetic engineering. Growers have always had the choice of which crops to grow, and they have had to contend with commingling, admixtures, and other contaminants in their crops (Ronald and Fouche, 2006). Studies of coexistence of major GE and non-GE crops in North America and the European Union (E.U.) have demonstrated that there has been no significant gene flow from GE crops and that GE and non-GE crops are coexisting with minimal adverse economic effects. (Gealy et.al, 2007; Brookes and Barfoot, 2003; Brookes and Barfoot, 2004(a) and (b)). In fact, one survey of organic growers indicated that a vast majority of growers (92%) had incurred no direct additional costs related to the presence of GMOs in agriculture (Walz 2004). Coexistence practices can be sufficient to maintain the integrity of a crop and the purity of seed, especially if there are economic/market motivations to implement coexistence practices, e.g., for organic farmers who receive higher price premiums for their crop (Ronald and Fouche, 2006). Agricultural seed producers are free to develop and produce crop seed varieties whether they are conventional, GE, or organic. Growers are free to cultivate the crops and crop varieties of their choice using the production systems they prefer. Growers are likewise free to market their GE or non-GE crop varieties and obtain price premiums for growing specific varieties for particular markets (e.g., using organic methods for a certain crop or producing a specialty crop variety for particular processing needs). Consumers are likewise free to choose either organic or non-organic products. Market impacts result from, and are affected by, these various private sector decisions and choices.

Review of Data and Analysis

10. As the APHIS Administrator, I am responsible for all APHIS programs, including BRS, and I am therefore the final decision maker for those programs. In my effort to propose a reasonable and appropriate remedy during the preliminary injunction remedial phase of this litigation, I have reviewed the record in this matter. I have also sought and reviewed information from officials in BRS regarding the relevant scientific issues, such as the risk, if any, of cross-pollination between Roundup Ready sugar beets (RRSB) and related species like Swiss chard and table beets. I have likewise reviewed the data provided by Dr. Rebecca L. Stankiewicz Gabel, a BRS expert, that identifies, based on the best data available to BRS, the locations of sugar beet, table beet, and chard seed and vegetable crop fields in the United States. Additionally, I have sought and reviewed USDA's Farm Service Agency's (FSA) data and analysis of the potentially severe economic impacts of a Court order enjoining the further planting, cultivation, processing, or other use of RRSB, including the flowering of any sugar beet seed crop, until further NEPA analysis is completed.

11. BRS has reviewed and analyzed the science and production practices of sugar beets and the related crops with which they can cross-pollinate. I have also reviewed the declaration of Dr. Neil Hoffman, a BRS expert, who has researched this issue. Dr. Hoffman found, as did Dr. Stankiewicz Gabel, that there is an extremely low risk of RRSB root crops cross-pollinating with Swiss chard and table beets crops because: 1) based upon information regarding the geographical distribution of RRSB root crops that BRS collected, there is proximity between RRSB root crops and Swiss chard and table beet vegetable crops. However, despite their proximity, there is no risk of gene flow when the crops are being harvested for their vegetable;

2) there is no proximity between RRSB root crops and Swiss chard and table beet seed crops; and 3) since the RRSB root crops are harvested before bolting, there is a very low likelihood that RRSB root crops would flower and produce pollen. (Hoffman Decl. at ¶¶ 41-46; Stankiewicz Gabel Decl. at ¶¶ 27, 29).

Dr. Hoffman also found that the risk of gene flow from the harvested RRSB root crops which are stored until they are processed is extremely low because the roots are processed and the genetic material is thereby destroyed before they have a chance to flower. (Hoffman Decl. at ¶¶ 62-63).

Dr. Hoffman further concluded that there is no risk of gene flow from processed sugar derived from RRSB. Such processed sugar has **no** GE component because it is solely made up of sucrose molecules and lacks any DNA. (Hoffman Decl. at ¶ 64.)

Regarding RRSB seed crops which are grown outside the Willamette Valley, Dr. Stankiewicz Gabel has concluded, based on the best available data, that there is no proximity to related crops such as Swiss chard and table beets (Stankiewicz Gabel Decl. at ¶¶ 21-22), and, therefore, the risk of cross-pollination is low.

With regard to the RRSB seed crops grown in the Willamette Valley, for reasons described in his declaration, Dr. Hoffman found that isolation distances currently required by the Willamette Valley Specialty Seeds Association (WVSSA) are adequate to minimize the risk of cross-pollination to less than 1 seed in 10,000. (Hoffman Decl. at ¶ 55). Based on both Dr. Hoffman's findings, and my personal knowledge and experience with GE crops including RRSB, I am of the opinion that these findings are accurate, valid and reliable, and therefore I have concluded that the risk of cross-pollination between RRSB and the plaintiffs' crops is very low under the current WVSSA isolation distance guidelines.

12. I have also reviewed the facts and analyses provided by a FSA expert, who analyzed and evaluated the harmful impacts plaintiffs' proposed injunction would have on the U.S. domestic sugar supply, on domestic sugar prices for U.S. consumers, and on the U.S. economy in general. These findings, made by Dr. Daniel Colacicco, Director of FSA's Dairy and Sweetener Analysis Group, in his declaration clearly show that if the Court enjoins the further planting, cultivation, processing, or other use of RRSB, including the flowering of any sugar beet seed crop as requested by Plaintiffs in their motion for preliminary injunction, the effects on the U.S. domestic sugar supply and on domestic sugar prices for U.S. consumers would be catastrophic. (Colacicco Decl. ¶¶ 11-33).

APHIS' Regulatory Authority Over GE Organisms under the PPA and Part 340 is Limited.

14. APHIS' regulatory authority over GE organisms under its Part 340 biotechnology regulations is pursuant to its plant pest authority under the Plant Protection Act (PPA) of 2000. The PPA is the Federal plant health statute that protects and safeguards plant health in the United States. As long as RRSB or any other GE plant or crop variety is a regulated article under Part 340, APHIS has regulatory control and legal jurisdiction over the regulated article. Once APHIS determines that RRSB, or any other GE plant or crop variety, is not likely to pose a plant pest risk, then APHIS must deregulate the GE plant or crop variety. Moreover, once a GE plant or crop variety is deregulated by APHIS, any and all decisions to grow, produce, process, or market that deregulated product are made by the biotechnology producers, the product processors, the individual private farmers, etc., and are so driven by market demand and preference.

15. In March of 2005, APHIS determined that RRSB posed no plant pest risk as defined in the PPA and applied in the Part 340 regulations. Once APHIS deregulated RRSB, it thereafter had no regulatory authority to impose mitigation measures or otherwise proscribe any restrictions on any actions affecting or related to the deregulated RRSB whether it was RRSB development, planting, harvesting, processing, selling, marketing, or any other action.

16. This Court has not reached the issue of whether APHIS' deregulation decision was valid under the Plant Protection Act. Nevertheless, even if the Court were to vacate APHIS' deregulation decision for RRSB, thereby returning RRSB to its status as a regulated article under Part 340, it is important for the Court to know that APHIS' only regulatory authority over RRSB would be regarding RRSB's likelihood of posing a plant pest risk. On remand, since the Court has not invalidated APHIS' PPA determination that RRSB is not likely to pose a plant pest risk, and since APHIS has already determined in its 2005 deregulation decision that RRSB is not likely to pose a plant pest risk, absent any new sound science indicating that RRSB would be likely to pose a plant pest risk, APHIS would have no regulatory authority to impose any mitigation measures or proscriptions of any kind on RRSB. And at this time, APHIS is not aware of any sound scientific information to change its determination that RRSB is not likely to pose a plant pest risk.

APHIS' Request that the Court Remand to APHIS to reevaluate and determine the appropriate environmental analysis for the deregulation of RRSB.

17. APHIS issued a final environmental assessment (EA) and a finding of no significant impact (FONSI) in March 2005 regarding its determination to deregulate RRSB, along with its determination that RRSB is not likely to pose a plant pest risk and should therefore be

deregulated pursuant to Part 340. The final EA and FONSI are now almost five years old. The Court found the final EA was inadequate for three reasons. However, APHIS is now aware of and has been gathering new, sound scientific information and analyses regarding those three issues since its March 2005 RRSB deregulation determination. Accordingly, APHIS requests that the Court give APHIS' BRS experts and scientists the opportunity to exercise their expertise in reevaluating and determining what additional NEPA environmental analysis is needed and appropriate for the deregulation determination of RRSB.

18. The current permitting and notification systems under part 340 are designed to regulate small scale field tests. APHIS does not have the resources nor the personnel to inspect and monitor the approximately 1.4 million acres that are now planted with GE sugar beets. Moreover, as explained in paragraph 16, even on remand, since the Court has not invalidated APHIS' PPA determination that RRSB is not likely to pose a plant pest risk, APHIS would have no regulatory authority to impose any mitigation measures or proscriptions of any kind on RRSB *unless* APHIS were to make a new determination that RRSB is likely to pose a plant pest risk. But, as also explained in paragraph 16, at this time, APHIS is not aware of any sound scientific information to change its determination that RRSB is not likely to pose a plant pest risk.

APHIS Does Not Believe Any Injunction is Needed while APHIS Completes the

Appropriate Environmental Analysis

19. Based on my review of the sound scientific evidence provided by the APHIS-BRS and FSA experts, the record, and my own experience and expertise, it is my professional opinion as the APHIS Administrator, that no preliminary injunction is needed for the deregulated RRSB.

For the reasons stated above, cross pollination by RRSB root crops to related species is extremely unlikely and cross-pollination by RRSB seed crops outside of the Willamette Valley is similarly improbable. Moreover, even within the Willamette Valley, where RRSB seed crops are grown in relatively closer proximity to seed crops of related species, the WVSSA, which imposes mandatory isolation distances for all members, provides sufficient measures to make cross-pollination unlikely. (Hoffman Decl at ¶¶ 26-27, 55). RRSB have been planted under the WVSSA requirements since early 2007. Since then, we are not aware of any instances where gene flow from RRSB into Swiss chard or table beet seed fields has occurred. In fact, recent evidence that plaintiff Frank Morton has been testing his crops for gene flow from RRSB and has not found any gene flow is indicative that these measures imposed by the WVSSA are adequate and are working as intended.

APHIS' Proposals to the Court Regarding Injunctive Remedies, if any, while

APHIS Completes the Appropriate Environment Analysis

20. APHIS has limited regulatory authority over regulated articles under 7 CFR Part 340 and the Plant Protection Act, and has no regulatory authority over a deregulated GE plant or crop variety. APHIS would again be able to regulate under Part 340 a deregulated article if new sound scientific evidence became available subsequent to the deregulation that indicated that the deregulated article was likely to pose a plant pest risk. However, at this time, APHIS is not aware of any such sound evidence regarding RRSB. Thus, given APHIS' lack of regulatory authority to impose restrictions on the deregulated RRSB, if the Court deems any injunctive remedy necessary at all, APHIS proposes that the Court adopt the measures APHIS has determined to be the most appropriate to address the potential for any gene flow.

Based on my knowledge and my 10 years of experience in being responsible for and dealing with Part 340 and GE organisms, in addition to all of the information and analysis I have reviewed in the record and in the other declarations from USDA scientists and experts prepared in connection with Federal Defendants' opposition to Plaintiffs' motion for preliminary injunction, as the APHIS Administrator, I respectfully propose that if any remedy is deemed necessary, the Court should confine the scope of any injunctive relief to the Willamette Valley in Oregon where there may be **some** potential concerns about the risk of cross-pollination between RRSB and nearby organic and conventional sugar beet, table beet or Swiss chard crops.

21. Sugar already refined from RRSB:

APHIS proposes that the Court not impose any injunctive remedy with respect to sugar from RRSB that has already been refined because, as explained earlier, such refined sugar is solely comprised of sucrose molecules, is identical to conventional sugar, and contains no GE protein or DNA. In all respects it is identical to sucrose derived from conventional sugarbeets (Hoffman Decl. at ¶ 64). The refined RRSB sugar poses no threat of gene flow. Id.

22. RRSB Sugar Beets harvested in 2009:

APHIS proposes that the Court not impose any injunctive remedy for already harvested RRSB root crops that are not yet processed. These harvested RRSB are sitting in large piles outdoors or in warehouses. (Hoffman Decl at ¶¶ 62-63). Processing these harvested sugar beets eliminates the possibility of gene flow because it will keep them from flowering and producing pollen that could play a role in gene flow. Id. As noted above, refined sugar contains no genetic material or protein.

23. RRSB root crops in 10 states:

APHIS proposes that the Court not impose any injunctive remedy for future RRSB root crops to be planted and cultivated for sugar production. Root crops do not normally flower, and any flowers can be easily removed if they occur. (Hoffman Decl at ¶ 44). Moreover, the RRSB root crops are not grown near seed crops for Swiss chard and table beet. (Stankiewicz Gabel Decl. at ¶ 29). Although California is another state where sugar beet is grown, no RRSB is grown in California at this time. RRSB root crops pose no risk of gene flow to Swiss chard and table beet vegetable and root crops. (Hoffman Dec. at ¶ 45).

24. RRSB Seed Crops outside the Willamette Valley:

APHIS also proposes that the Court not impose any injunctive remedy with regard to RRSB seed crops outside of the Willamette Valley, Oregon, because there are unlikely to be any recipient flowering plants in proximity. Dr. Stankiewicz-Gabel analyzed data from the FSA to identify any States where sugar beet seed are produced. (Stankiewicz Gabel Decl. at ¶ 18.). Dr. Stankiewicz Gabel determined that sugar beet seed are being produced in OR (74%), MI (9%), WA (6%), NE (6%), MN (2%), ID (2%); CA (1%). *Id.* Dr. Stankiewicz Gabel then looked for counties in these States that grow both sugar beet seed and table beet seed or chard seed and determined that, based on the FSA data, only Oregon had a county, in the Willamette Valley, where sugar beet seed and table beet seed occurred in the same county. (Stankiewicz Gabel Decl. at ¶¶ 21-22). Although not reflected in the FSA data, the plaintiffs assert that they grow Swiss chard seed in the Willamette Valley.

25. RRSB seed crops in the Willamette Valley:

APHIS has determined that the only area in the United States where there are commercial seed crops of RRSB and organic Swiss chard and table beets growing in the same proximity is the Willamette Valley in Western Oregon where there are a limited number of organic growers

of Swiss chard and table beet. This is the only area where gene flow from RRSB to Swiss chard or table beet is even remotely possible. Conventional seed growers for chard are mainly found in Washington and California and conventional table beet seed growers are mainly in Washington. The remote potential for gene flow from RRSB in Western Oregon is primarily limited to the organic growers of Swiss chard and table beet seed. (Stankiewicz Gabel Decl. at ¶¶ 21-23; Hoffman Decl. at ¶ 50). The *Beta* species seed crops in the Willamette Valley are currently being grown under isolation distances imposed by the WVSSA on all of its members. The isolation distance imposed between RRSB or conventional sugar beets (hybrids) and Swiss chard or table beets (open pollinators) is 4 miles. This is the status quo in the Willamette Valley.

As Dr. Hoffman concluded, gene flow dramatically declines with distance, falling to about 0.1% at 0.3 miles (500 meters) under conditions where there is no competition from a local pollen source. (Hoffman Decl at ¶¶ 31-34). He further noted that the 4-mile isolation distance is more than 12 times the distance needed to reduce cross-pollination with sexually compatible species down to 0.1% (1 seed in 1000) and concluded that competition from local pollen production together with the greater isolation distance will further reduce the likelihood of cross pollination by at least an order of magnitude, to less than 1 seed in 10,000 seeds. (Hoffman Decl. at ¶ 55). Therefore, the 4 mile isolation distance is effective to limit cross-pollination to negligible levels between RRSB and related *Beta* species, regardless of whether the RRSB is male sterile or non-male sterile.

As Dr. Hoffman concluded, when male sterile parents carry the GE trait in RRSB seed production, they produce a very small amount of pollen and no isolation distance is needed to prevent transmission of the GE trait from RRSB to related *Beta* species. (Hoffman Decl. at ¶ 41). Nonetheless, these crops are still grown under the 4 mile isolation distance requirements of

the WVSSA in order to address seed purity concerns, not necessarily related to GE, between growers of all types of related *Beta* species.

Imposing isolation distances beyond 4 miles would mean that fewer farmers will be able to raise sexually compatible crops in the Willamette Valley. For example, if a 10 mile isolation distance were imposed on related *Beta* species, a maximum of only 12 hybrid and open pollinated *Beta* species farmers could coexist in the Willamette Valley. Under the current 4 mile isolation distance requirements 80 farmers of related *Beta* species can coexist. Such a drastic measure as imposing a 10 mile isolation distance will greatly diminish the potential for coexistence in the presence of valid scientific evidence showing that it is not needed. Further, any change in isolation distances could potentially be disruptive to the WVSSA.

Based on my review of this information, APHIS proposes that if the Court finds a remedy necessary, it should make mandatory in the Willamette Valley in Oregon the 4-mile WVSSA isolation distance that applies to RRSB and related *Beta* species. As discussed above, because APHIS lacks regulatory authority over deregulated articles, it does not have authority to enforce any mandatory isolation distances and has limited resources for doing so. APHIS believes that establishing the details related to enforcement of any mandatory isolation distances needs the input of the parties, as well as input from entities such as the WVSSA or other growers of *Beta* crops located in the Willamette Valley. APHIS requests that the Court permit the parties as well as potentially affected entities the opportunity to confer regarding appropriate enforcement mechanisms for any mandatory isolation distances and allow APHIS to submit a proposal to the Court thereafter.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 12 day of February 2010, in Washington, D.C.


Cindy J Smith, APHIS Administrator